UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF NEW YORK

GENEVIEVE T. WEBB,

Plaintiff,

vs. **5:19-CV-1604 (MAD/ML)**

MENTOR WORLDWIDE LLC and JOHNSON & JOHNSON SERVS., INC.,

Defendants.

APPEARANCES:	**OF COUNSEL:**
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Mae A. D'Agostino, U.S. District Judge:

MEMORANDUM-DECISION AND ORDER

I. INTRODUCTION

On October 23, 2019, Plaintiff Genevieve T. Webb ("Plaintiff") filed a complaint in the Supreme Court of Onondaga County against Defendant Mentor Worldwide LLC ("Mentor") and Johnson & Johnson Services, Inc. ("Johnson & Johnson") (collectively, "Defendants"). *See* Dkt. No. 2. Plaintiff alleges what the Court construes to be claims of negligence based on failure to warn and manufacturing defect, negligence *per se*, strict liability design and manufacturing defect, breach of implied warranty, and breach of express warranty. *See id.* On December 24, 2019, Defendants removed the action to the Northern District of New York pursuant to 28 U.S.C. § 1332(a). Dkt. No. 1 at 1. On January 23, 2020, Defendants filed a motion to dismiss, which is currently before the Court. *See* Dkt. No. 10.

II. BACKGROUND

Plaintiff commenced this action in Onondaga County Supreme Court on October 23, 2019 against Defendants. *See* Dkt. No. 2 at ¶¶ 2-4. Plaintiff's claims stem from breast augmentation surgery, whereupon Mentor Worldwide MemoryGel mammary prostheses ("MemoryGel Implants") were implanted in Plaintiff's body on October 24, 2016. *See id.* at ¶¶ 8–12. Plaintiff alleges that, within two months of this surgery, she started developing various physical symptoms and ailments, ultimately resulting in a course of treatment that included pain injections, neck surgery, instrumental fusion with the placement of permanent metal rods in her back, and the installation of a bone stimulator in her neck. *See id.* at ¶¶ 13–39. Plaintiff also claims that she suffers from "Breast Implant Illness," symptoms of which include "fatigue, pain, hair loss, headaches, chills, photosensitivity, chronic pain, itchy dry skin, inflammation, muscle spasms, anxiety, brain fog, sleep disturbance, depression, neurological issues, autoimmune ailments, and hormonal issues." *Id.* at ¶¶ 41–47. Plaintiff further alleges that, on July 10, 2019, she underwent

urine testing which indicated she suffered from metal poisoning resulting from the MemoryGel Implants. *See id.* at ¶ 41.

Defendants have moved to dismiss Plaintiff's complaint, arguing that Plaintiff's claims are preempted by the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et sq.* ("FDCA"), pursuant to the Medical Device Amendments of 1976, 21 U.S.C. § 360c ("MDA"), or, alternatively, that Plaintiff has failed to state any claims upon which relief could be granted. *See* Dkt. No. 10-1. Plaintiff opposes Defendants' motion, claiming that her allegations are not preempted and, alternatively, are sufficiently pled to survive Defendants' motion to dismiss. *See* Dkt. No. 15.

III. DISCUSSION

A. Standard of Review

A motion to dismiss for failure to state a claim pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure tests the legal sufficiency of the party's claim for relief. *See Patane v. Clark*, 508 F.3d 106, 111–12 (2d Cir. 2007). In considering the legal sufficiency, a court must accept as true all well-pleaded facts in the pleading and draw all reasonable inferences in the pleader's favor. *See ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 98 (2d Cir. 2007) (citation omitted). This presumption of truth, however, does not extend to legal conclusions. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citation omitted). Although a court's review of a motion to dismiss is generally limited to the facts presented in the pleading, the court may consider documents that are "integral" to that pleading, even if they are neither physically attached to, nor incorporated by reference into, the pleading. *See Mangiafico v. Blumenthal*, 471 F.3d 391, 398 (2d Cir. 2006) (quoting *Chambers v. Time Warner, Inc.*, 282 F.3d 147, 152–53 (2d Cir. 2002)).

To survive a motion to dismiss, a party need only plead "a short and plain statement of the claim," *see* Fed. R. Civ. P. 8(a)(2), with sufficient factual "heft to 'sho[w] that the pleader is entitled to relief.'" *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 557 (2007) (quotation omitted). Under this standard, the pleading's "[f]actual allegations must be enough to raise a right of relief above the speculative level," *see id.* at 555 (citation omitted), and present claims that are "plausible on [their] face," *id.* at 570. "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Iqbal*, 556 U.S. at 678 (citation omitted). "Where a complaint pleads facts that are 'merely consistent with' a defendant's liability, it 'stops short of the line between possibility and plausibility of "entitlement to relief."'" *Id.* (quoting [*Twombly*, 550 U.S.] at 557, 127 S. Ct. 1955). Ultimately, "when the allegations in a complaint, however true, could not raise a claim of entitlement to relief," or where a plaintiff has "not nudged [its] claims across the line from conceivable to plausible, the[] complaint must be dismissed[,]" *Twombly*, 550 U.S. at 558, 570.

B. Statutory and Regulatory Background

"The MDA established a system of federal oversight for the introduction of new medical devices. Devices are organized into three different classes, with Class III receiving the most federal oversight." *Bertini v. Smith & Nephew, Inc.*, 8 F. Supp. 3d 246, 251 (E.D.N.Y. 2014) (citing *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008)). A device is assigned to Class III if "there are not any less stringent classifications which would reasonably assure the device's safety and effectiveness, and the device is '"purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health," or "presents a potential unreasonable risk of illness or injury."'" *Id.* (quoting *Riegel*, 552 U.S. at 317 (quoting 21 U.S.C. § 360c(a)(1)(C)(ii))).

New Class III devices must be approved through the pre-market approval ("PMA") process, which requires a device manufacturer to provide the Food and Drug Administration ("FDA") with "reasonable assurance" that its device is safe and effective. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996). PMA is a "rigorous" process. *Id.* "To be awarded PMA, a device manufacturer must submit a substantial application including

> full reports of all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the applicant; a "full statement" of the device's "components, ingredients, and properties and of the principle or principles of operation"; "a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device"; samples or device components required by the FDA; and a specimen of the proposed labeling.

Olmstead v. Bayer Corp., No. 3:17-CV-387, 2017 WL 3498696, *1 (N.D.N.Y. Aug. 15, 2017) (quoting *Riegel*, 552 U.S. at 318 (quoting 21 U.S.C. § 360e(c)(1))). The FDA must weigh "'any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.'" *Riegel*, 552 U.S. at 318 (quoting 21 U.S.C. § 360c(a)(2)(C)). Therefore, the FDA may "approve devices that present great risks if they nonetheless offer great benefits in light of available alternatives." *Id.*

"After PMA is issued, 'the MDA forbids a manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." *Olmstead*, 2017 WL 3498696, at *1 (quoting *Riegel*, 552 U.S. at 319 (citing 21 U.S.C. § 360e(d)(6)(A)(i) (now at § 360e(d)(5)(A)(i)))). Furthermore, the manufacturer "must inform the FDA if it learns new information about the device and must report when the device has caused or contributed to death or serious injury." *Id.* (citing *Riegel*, 552 U.S. at 319 (citing 21 C.F.R. § 803.50(a))). If at any time the FDA determines

a device is unsafe or ineffective "under the terms of its labeling, it may withdraw premarket approval." *Id.* (citing *Riegel*, 552 U.S. at 319–20 (citing 21 U.S.C. § 360e(e)(1))).

The MDA includes a preemption provision, 21 U.S.C. § 360k ("§ 360k"), which prevents:

> any "State or political subdivision of a State" from establishing or continuing in effect any requirement, with respect to a device intended for human use, which "(1) is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter."

Bertini, 8 F. Supp. 3d at 251 (quoting 21 U.S.C. § 360k). Because § 360k applies only to "state requirements 'different from, or in addition to, any requirement applicable . . . to the device' under federal law," a court must first "determine whether the Federal Government has established requirements applicable" to the device at issue. *Riegel*, 552 U.S. at 321 (quoting 21 U.S.C. § 360k).

"The Supreme Court has partly explained the contours of federal pre-emption under MDA Section 360k(a)." *Gale v. Smith & Nephew, Inc.*, 989 F. Supp. 2d 243, 247–48 (S.D.N.Y. 2013). First, in *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), "the Supreme Court . . . held that a state law claim is impliedly preempted under the FDCA if the conclusion that the state law has been violated is based solely on a violation of the FDCA rather than on some independent state law duty." *Nagel v. Smith & Nephew, Inc.*, No. 3:15-CV-00927, 2016 WL 4098715, *3 (D. Conn. July 28, 2016) (citing *Buckman*, 531 U.S. at 349). Then, in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), the Supreme Court "ruled on whether Section 360k(a) expressly pre-empted state tort law." *Gale*, 989 F. Supp. 2d at 248. In *Riegel*, the Supreme Court held that "[s]tate requirements are pre-empted under the MDA only to the extent that they are 'different from, or in addition to' the requirements imposed by federal law." *Riegel*, 552 U.S. at 330 (quoting 21 U.S.C.

§ 360k(a)(1)). However, *Riegel* "observed that the MDA preemption provision does not bar a state from providing a damages remedy for claims premised on the violation of FDA regulations, because 'the state duties in such a case "parallel," rather than add to, federal requirements.'" *Burkett v. Smith & Nephew Gmbh*, No. CV 12-4895, 2014 WL 1315315,*2 (E.D.N.Y. Mar. 31, 2014) (quoting *Riegel*, 552 U.S. at 330).

"Courts have reconciled *Riegel* and *Buckman* to 'create a narrow gap through which a plaintiff's state-law claim must fit if it is to escape express or implied preemption.'" *Gale*, 989 F. Supp. 2d at 248 (quoting *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010)). "The plaintiff must be suing for conduct that violates the FDCA (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing because the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*)." *Sprint Fidelis Leads*, 623 F.3d at 1204 (quotation and emphasis omitted). "In other words, the plaintiff's state-law claim must 'parallel[ ] a federal-law duty under the MDA' but also exist 'independent[ly]' of the MDA." *A.F. By & Through Fogel v. Sorin Grp. USA, Inc.*, 346 F. Supp. 3d 534, 541 (S.D.N.Y. 2018) (quoting *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1233 (9th Cir. 2013)).

The MemoryGel Implants at issue are Class III medical devices, which have been approved by the FDA through the PMA process on November 17, 2006. *See* Dkt. No. 10-2. Premarket approval was a federal requirement imposed on the MemoryGel Implants, and Plaintiff's claims relate to their safety and effectiveness. *See generally* Dkt. No. 2. Therefore, Plaintiff's state law claims will not be preempted by § 360k of the MDA if they are not different from or in addition to federal law, *Riegel*, 552 U.S. at 330, and will stand if they meet the pleading requirements at the motion to dismiss phase.

C. Plaintiff's Claims

To succeed in asserting a claim that fits through the "narrow gap" between express and implied preemption, Plaintiff must identify a parallel federal law upon which she has based her state-law claims. *See Olmstead*, 2017 WL 3498696, at *4. Defendants contend that "Plaintiff does not even attempt to allege that any alleged federal violation also constitutes a violation of parallel state duties." Dkt. No. 10-1 at 15. In response, Plaintiff describes the complaint as alleging that Defendants did not comply with the FDA's Quality System Regulations and Current Good Manufacturing Practices, and that "it is clear from the allegations in the Verified Complaint that Plaintiff's state law claims are parallel to the MDA requirements and therefore are not preempted by the MDA." Dkt. No. 15 at ¶¶ 85, 87.

While Plaintiff refers to the Current Good Manufacturing Practices ("CGMPs"), *see* 21 C.F.R. § 820.1 *et seq*., Plaintiff fails to explain how Defendants violated the CGMPs. Courts in the Second Circuit and elsewhere have determined that the CGMPs "'are intended to serve only as "an umbrella quality system" providing "general objectives" medical device manufacturers must seek to achieve.'" *Olmstead*, 2017 WL 3498696, at *4 (quoting *Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271, 278–79 (E.D.N.Y. 2009) (quotation omitted)); *see also Sprint Fidelis Leads*, 592 F. Supp. 2d at 1157 (referring to the CGMPs as "simply too generic, standing alone, to serve as the basis for Plaintiff's manufacturing-defect claims").[1] "Since these regulations are open to a particular manufacturer's interpretation, allowing them to serve as a basis for a claim would lead to differing safety requirements that might emanate from various lawsuits." *Olmstead*, 2017 WL

[1] Despite Plaintiff's argument that she cannot adequately plead facts without discovery, *see* Dkt. No. 15 at ¶ 93, courts have found solely basing claims on the CGMPs as insufficient, despite the "challenge of a plaintiff to plead such a claim prior to discovery." *Pearsall v. Medtronics Inc.*, 147 F. Supp. 3d 188, 197–98 (E.D.N.Y. 2015) (citing *Spring Fidelis Leads*, 592 F. Supp. 2d. at 1207).

3498696, at *4 (quoting *Ilarraza v. Medtronic, Inc.*, 677 F. Supp. 2d 582, 588 (E.D.N.Y. 2009)). Thus, allowing a suit to continue on the basis of the CGMPs would necessarily impose "standards that are 'different from, or in addition to' those imposed by the MDA—precisely the result that the MDA preemption provision seeks to prevent." *Id.* (quoting *Ilarraza*, 677 F. Supp. 2d at 588).[2]

Some courts have found that violations of the CGMP regulations could conceivably serve as a basis for claims; however, these decisions "do not excuse the Plaintiff from identifying the specific CGMP regulations at issue and providing 'sufficient factual detail' to substantiate her allegations." *Green v. Medtronic, Inc.*, No. 1:19-CV-3242, 2019 WL 7631397, *5 (N.D. Ga. Dec. 31, 2019) (quoting *Cline v. Advanced Neuromodulation Sys., Inc.*, 921 F. Supp. 2d. 1374, 1379 (N.D. Ga. 2012)); *see also Weber v. Allergan, Inc.*, 940 F.3d 1106, 1114 (9th Cir. 2019) (collecting cases). Therefore, the Court will examine the merits of whether Plaintiff's claims could survive preemption, despite Plaintiff's reliance on the CGMPs as the source of Defendants' alleged violations.

In the alternative, Plaintiff's generalized allegations cannot withstand preemption because they fail to establish the necessary link between Defendants' federal violations and her alleged causes of action. *See Horowitz*, 613 F. Supp. 2d at 280. "The generalized allegations made in plaintiff's complaint call for such amplification here as the relationship between defendants' federal violations and plaintiff's injury seems implausible." *Id.* at 283 (citing *Heisner v. Genzyme Corp.*, No. 08–C–593, 2008 WL 2940811, *5 (N.D. Ill. July 25, 2008) (finding that "Plaintiff's

[2] While other cases in the Northern District of New York had held prior to *Olmstead* that an allegation that a defendant violated either the PMAs or the CGMPs could avoid preemption, this outcome requires the claims be "supported by sufficient factual evidence of the violation and demonstrate a causal connection to the alleged injuries . . . ." *Rosen v. St. Jude Med., Inc.*, 41 F. Supp. 3d 170, 181 (N.D.N.Y. 2014). However, as discussed in more detail below, Plaintiff's complaint is neither supported by sufficient factual evidence nor does it it demonstrate a causal connection to the alleged injuries. *See id.*

vague suggestion that Defendant violated [FDA] reporting requirements does not help Plaintiff avoid dismissal of his claims; Plaintiff has not alleged anything in his complaint that would put Defendant on notice that the basis of Plaintiff's claim was [Defendant's] failure to meet reporting requirements")).

In an effort to satisfy the pleading standard and bring forth facts demonstrating the parallel nature of her claims, Plaintiff points to a warning letter issued by the FDA. *See* Dkt. No. 15-2. However, this letter relates to a different product than the one at issue – the letter relates to MemoryShape Implants (P060028), not to Plaintiff's MemoryGel Implants (P030053). *Compare id.*, *with* Dkt. No. 10-2. The MemoryShape Implants received separate FDA approval and are subject to a different set of post-approval requirements than the MemoryGel Implants that Plaintiff received. *See* Dkt. No. 16 at 4.

The Court finds that Plaintiff's defective manufacturing claims should be dismissed. "To plead and prove a manufacturing flaw under either negligence or strict liability, the plaintiff must show that a specific product unit was defective as a result of 'some mishap in the manufacturing process itself, improper workmanship, or because defective materials were used in construction,' and that the defect was the cause of plaintiff's injury." *Horowitz*, 613 F. Supp. 2d at 283 (quoting *Colon ex rel. Molina v. BIC USA, Inc*., 199 F. Supp. 2d 53, 85 (S.D.N.Y. 2001)). Plaintiff must, therefore, show that her specific MemoryGel Implants were defective. The complaint's generic allegations of a defective manufacturing claim do not demonstrate that they are based on Defendants' violation of federal regulations. *See id.* (citing *Stevens v. Pacesetter, Inc.*, No. 07–CV–3812, 2008 WL 2637417, *1 (D.S.C. Apr. 1, 2008) (finding that although "[t]he complaint contains a few generic allegations of a manufacturing defect[,] [t]hese allegations do not, however, suggest that the particular alleged failure is a failure to manufacture the device in

accordance with federal standards")). Without specific allegations explaining how Defendants' manufacturing process was in violation of federal requirements so that the MemoryGel Implants were defective, Plaintiff's claims fall directly within the MDA's preemption provision.

Plaintiff's failure-to-warn and design defect claims are also preempted because they "seek to impose safety-related requirements on the device or its labeling beyond those imposed by the FDA." *Otis-Wisher v. Medtronic, Inc.*, 616 Fed. Appx. 433, 434 (2d Cir. 2015) (citing *Riegel*, 552 U.S. at 321–30). With regards to the failure-to-warn claims, "[a]llowing the claim[s] to proceed would permit a jury to find that defendants were required 'to provide warnings above and beyond those on the [MemoryGel Implants] product label—a label that was specifically approved by the FDA as part of the PMA process.'" *Horowitz*, 613 F. Supp. 2d at 286–87 (quoting *Sprint Fidelis Leads*, 592 F. Supp. 2d at 1159).[3] With regards to the design defect claims, Plaintiff's challenges, including that "the Mentor Breast Implants at issue did not meet the design . . . specifications," necessarily impose requirements that are different from, or in addition to, federal regulations. *See* Dkt. No. 2 at ¶ 88; *see also Berish v. Richards Med. Co.*, 928 F. Supp. 185, 191–92 (N.D.N.Y. 1996) (stating that courts have reasoned that "the extensive, premarket regulatory scheme applicable to Class III devices, because of the devices' potential unreasonable risk of illness or injury, imposes requirements relating to design and manufacture that would preempt state law claims relating to the same") (internal citation and quotations omitted).

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[3] Even if Plaintiff's failure to warn claims were somehow able to survive preemption, "New York's learned intermediary doctrine provides that 'the manufacturer of a medical device does not have a duty to directly warn a patient of risks associated with the device, but instead discharges its duty by providing the physician with sufficient information concerning the risks of the device.'" *Id.* at 287 n.9 (quoting *Sita v. Danek Med., Inc.*, 43 F. Supp. 2d 245, 259 (E.D.N.Y. 1999)). Plaintiff's complaint contains only conclusory allegations that the MemoryGel Implants "contained warnings which were insufficient to alert consumers," which is inadequate to avoid dismissal. Dkt. No. 2 at ¶ 61.

Accordingly, these claims are expressly preempted under § 360k(a). *See Otis-Wisher*, 616 Fed. Appx. at 434.

In order to recover under a breach of implied warranty of merchantability claim, Plaintiff must establish that the MemoryGel Implants were not "reasonably fit for the ordinary purpose for which it was intended." *Denny v. Ford Motor Co.*, 87 N.Y.2d 248, 265 (1995). While Plaintiff alleges that Defendants "breached the implied warranty of merchantability," she has failed to allege that Defendants' federal violations caused the MemoryGel Implants to have deviated from their purpose, that they failed, or that they were unfit for patients. *See generally* Dkt. No. 2. For Plaintiff to succeed on her claim, "a jury would have to find that defendants breached the implied warranty of merchantability by manufacturing a medical device that was unsafe in its federally approved design or manufacture." *Horowitz*, 613 F. Supp. 2d at 284 (citing *Sprint Fidelis Leads*, 592 F. Supp. 2d at 1164). Such a claim falls squarely within the MDA's preemption provision.

Plaintiff's breach of express warranty claim is preempted to the extent that it is premised on FDA approved representations made by the manufacturer. *See id.* at 285 (citing *Lake v. Kardjian*, 874 N.Y.S.2d 751, 754 (N.Y. Sup. Ct. 2008) (finding that "a breach of express warranty claim based upon FDA approved statements in product labeling and advertising is preempted by the MDA, because such a claim would impose requirements different from, or in addition to, the federal requirements, potentially resulting in the imposition of liability on a manufacturer who has fully complied with federal law")). "To permit a jury to decide [the plaintiff's] claims that the information, warnings, and training material the FDA required and approved through the PMA process were inadequate under state law would displace the FDA's exclusive role and expertise in this area and risk imposing inconsistent obligations on [defendants]." *Id.* (quoting *Rollins v. St. Jude Med.*, 583 F. Supp. 2d 790, 797–98 (W.D. La. 2008)). In her complaint, Plaintiff broadly

alleges that "Defendants breached their express warranty because the Breast Implants were not fit for the ordinary purpose in which such goods are used." Dkt. No. 2 at ¶ 113. In order to avoid preemption, the plaintiff's breach of express warranty claim must "identify specific representations of the manufacturer which exceed the scope of the FDA approved statements, thereby establishing a contractual obligation voluntarily entered into by the manufacturer." *Lake*, 874 N.Y.S.2d at 754. Plaintiff has failed to identify such specific representations, and therefore, her claim fails to survive Defendants' motion to dismiss. *See, e.g.*, *id.* at 755 ("[P]laintiff has not identified any specific statements by [the defendant] which would constitute an express warranty, and has thereby failed to establish the existence of a claim which would escape federal preemption and survive this motion to dismiss").

Plaintiff has failed to identify a single parallel federal statute or regulation related to any of her claims beyond the CGMPs. Moreover, even if the Court were to accept Plaintiff's reliance on the CGMPs, Plaintiff's generalized allegations fail to establish the necessary link between Defendants' alleged federal violations and her alleged causes of action. *See Bryant v. Thoratec Corp.*, 343 F. Supp. 3d 594, 610 (S.D. Miss. 2018) ("The key distinction between the complaints that are sufficient to withstand a motion to dismiss and those that are not is not reliance on CGMPs but rather the existence of a manufacturing defect caused by a violation of federal regulation *and* allegations connecting a defect in the manufacture of the specific device to the plaintiff's specific injury") (internal quotation omitted) (emphasis in original). Plaintiff has alleged no facts that connect the claims to her specific injuries. *See id.* Plaintiff's claims also fail because they "amount to nothing more than conclusory allegations and 'naked assertion[s] devoid of further factual enhancement.'" *McConologue v. Smith & Nephew, Inc.*, 8 F. Supp. 3d 93, 110 (D. Conn. 2014) (quoting *Iqbal*, 556 U.S. at 678).

Plaintiff cannot fit her state-law claims through the "narrow gap" to escape preemption. *Gale*, 989 F. Supp. 2d at 248. Therefore, the Court concludes that, as a matter of law, the MDA preempts Plaintiff's claims.

D. Claims Against Defendant Johnson & Johnson

To the extent that Plaintiff purports to assert these claims against Defendant Johnson & Johnson, the Court finds that the claims are subject to dismissal. Rule 8 of the Federal Rules of Civil Procedure mandates that a complaint include sufficient allegations to provide "each defendant fair notice of what the plaintiff's claim is and ground upon which it rests." *Atuahene v. City of Hartford*, 10 Fed. Appx. 33, 34 (2d Cir. 2001) (internal quotation marks omitted); *see also Simmons v. Abruzzo*, 49 F.3d 83, 86 (2d Cir. 1995).

The complaint only refers to Defendant Johnson & Johnson insofar as Plaintiff states that: (1) "[t]he Johnson & Johnson corporate family includes a multitude of wholly owned subsidiaries and affiliated companies, including Mentor Worldwide, LLC. The Johnson & Johnson entities are so interwoven that they act as a single entity"; and (2) "each of the defendants was an agent, servant, employee, partner, alter ego, aider and abettor, co-conspirator and or joint venture of each of the remaining defendants . . . and each Defendant has ratified and approved the acts of each of the remaining Defendants." *See* Dkt. No. 2 at ¶¶ 4–5. Plaintiff does not refer to Defendant Johnson & Johnson after that point, and indiscriminately lumps Defendant Johnson & Johnson and Defendant Mentor together. Indeed, in her opposition to the motion to dismiss, Plaintiff does not address this argument, stating only that "there is absolutely no requirement that [Plaintiff] plead in any more of a specific manner than she did . . . [and] [e]ach of the claims . . . [are] clear and sufficient to place to the Defendant on notice . . . ." Dkt. No. 15 at ¶¶ 91–92.

Courts in this Circuit have found that purely conclusory allegations of alter-ego status will similarly not survive a motion to dismiss. *See, e.g.*, *Consol. Risk Servs., Inc. v. Auto. Dealers WC Self Ins. Tr.*, No. 1:06-CV-871, 2007 WL 951565, *5 (N.D.N.Y. Mar. 27, 2007) (internal citations omitted); *@Wireless Enters., Inc. v. AI Consulting LLC*, No. 05-CV-6176, 2006 WL 3370696, *6 (W.D.N.Y. Oct. 30, 2006) (citations omitted); *In re Currency Conversion Fee Antitrust Litig.*, 265 F. Supp. 2d 385, 426 (S.D.N.Y. 2003) ("Plaintiffs have failed to allege any facts to support their conclusion that the bank holding companies exercised such dominion and control over its subsidiaries. The unadorned invocation of dominion and control is simply not enough. For example, there is no allegation as to how or why the holding companies have dominion and control over the subsidiaries") (citations omitted). As stated above, Plaintiff's averments regarding the relationship between Defendants are very limited, and do not assert, beyond conclusory allegations, that Defendant Johnson & Johnson controls or dominates Defendant Mentor or that Defendant Mentor was Defendant Johnson & Johnson's instrumentality or alter ego. *See Consol. Risk Servs., Inc.*, 2007 WL 951565, at *5.[4]

Plaintiff's references to this Defendant are so vague that any claim against them are not sufficiently stated and therefore dismissed. *See Atuahene*, 10 Fed. Appx. at 34 ("By lumping all the defendants together in each claim and providing no factual basis to distinguish their conduct, [the plaintiff's] complaint failed to satisfy th[e] minimum standard [set forth in Rule 8]"); *Ying Li v. City of N.Y.*, 246 F. Supp. 3d 578, 598 (E.D.N.Y. 2017) ("Pleadings that do not differentiate which defendant was involved in the unlawful conduct are insufficient to state a claim").

E. Opportunity to Amend

[4] The Court notes that Defendants claim that Defendant Johnson & Johnson is not even Defendant Mentor's corporate parent. *See* Dkt. No. 10-1 at 25.

In her response to Defendants' motion to dismiss, Plaintiff requests, for the first time, leave to replead her claims against Defendants. *See* Dkt. No. 15 at ¶¶ 97–101. According to Rule 15 of the Federal Rules of Civil Procedure, when unable to amend as a matter of course, "a party may amend its pleading only with the opposing party's written consent or the court's leave." Fed. R. Civ. P. 15(a)(2). Local Rule 7.1(a)(4) states that "[a] party moving to amend a pleading . . . must attach an unsigned copy of the proposed amended pleading to its motion papers. *See* N.D.N.Y. Local Rule 7.1(a)(4). Additionally, unless otherwise stated, all motions require a memorandum of law detailing the reasons why the party believes their motion should be granted. *See* N.D.N.Y. Local Rule 7.1(a)(1). The Court's Individual Rules and Practices specifically outline that "[m]otions to dismiss . . . in civil cases will be decided '**with prejudice**' where the opposing party has been given the opportunity to amend the pleadings after receiving the moving party's pre-motion letter." Individual Rules and Practices of Hon. Mae A. D'Agostino, § 2(A)(ii) (emphasis in original).

Defendants filed a pre-motion letter regarding their motion to dismiss on December 27, 2019. *See* Dkt. No. 7. Plaintiff had the opportunity to amend her complaint after being served with the pre-motion letter, yet failed to do so. *See* Dkt. No. 10. Additionally, Plaintiff failed to comply with the requirements of the Local Rules, in she failed to submit a proposed amended complaint or memorandum of law in support of her application to amend.

As such, Plaintiff's request to amend her complaint is denied.

IV. CONCLUSION

After carefully reviewing the record in this matter, the parties' submissions and the applicable law, and for the above-stated reasons, the Court hereby

ORDERS that Defendants' motion to dismiss is **GRANTED** in its entirety; and the Court further

ORDERS that Plaintiff's complaint is **DISMISSED with prejudice**; and the Court further

ORDERS that the Clerk of the Court shall enter judgment in Defendants' favor and close this case; and the Court further

ORDERS that the Clerk of the Court shall serve a copy of this Memorandum-Decision and Order on the parties in accordance with the Local Rules.

IT IS SO ORDERED.

Dated: April 7, 2020
Albany, New York

Mae A. D'Agostino
U.S. District Judge